DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 7, 2015

Implanet S.A.
% Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K143759
Trade/Device Name: JAZZ System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: April 15, 2015
Received: April 15, 2015

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K143759

Device Name
JAZZ System

Indications for Use *(Describe)*

JAZZ is a temporary implant to be used in orthopedic surgery. The JAZZ system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1 Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2 Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3 Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ System may also be used in conjunction with other medical implants made of titanium alloy whenever "wiring" may help secure the attachment of other implants.

The JAZZ System is intended to be used with the Implanet Spine System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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K143759
510(k) SUMMARY

Implanet S.A.'s JAZZ System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Implanet S.A.
Technopole Bordeaux Montesquieu
Allee Francois Magendie – 33650 Martillac
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Contact Person: Regis Le Couedic, Director of Quality and Regulatory Affairs; Chief Technology Officer

Date Prepared: April 15, 2015

Name of Device

JAZZ System

Common Name / Classification Name

Bone fixation cerclage (21 C.F.R. 888.3010, Class II) (Product Code: OWI)

Predicate Devices

Implanet S.A.'s JAZZ System (K133617) (Primary)
Implanet S.A.'s JAZZ System (K121541) (Additional)

Purpose of the 510(k) Notice

The subject device is a modification to the cleared JAZZ System. Specifically, the proposed modification involves an expansion of the sizes of connectors available with the system, as well as several minor modifications to instrumentation.

Intended Use

JAZZ is a temporary implant to be used in orthopedic surgery. The JAZZ system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1 Spinal trauma surgery, used in sublaminar or facet wiring techniques;

2 Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3 Spinal degenerative surgery, as an adjunct to spinal fusions.

The JAZZ System may also be used in conjunction with other medical implants made of titanium alloy whenever "wiring" may help secure the attachment of other implants.

The JAZZ System is intended to be used with the Implanet Spine System.

Device Description

The Implanet JAZZ System is part of a spinal posterior fixation system that is designed to provide a stable interface between spinal constructs and the rod used in spinal surgery. The device is secured around vertebral structures such as the lamina, facet, or transverse processes from T1 to L5. The modified JAZZ System is designed to function in the same manner as the cleared predicate device. The JAZZ System is intended to be used with the Implanet Spine System (K143731).

Technological Characteristics

The JAZZ System consists of the following components and accessories: polyester (polyethylene-terephthalate) braid; titanium alloy connector and screw; and stainless steel malleable strip and buckle. The principal design modifications described in this submission include additional sizes of connector available and several minor modifications to the instruments. All changes were evaluated via risk analysis. No new risks were identified in verification and validation testing.

Performance Data

Mechanical testing performed for Implanet S.A.'s JAZZ System in accordance with ASTM F1717, static tensile testing, and dynamic tensile testing, confirmed that the product met the necessary specifications and functioned as intended. Sterilization and shelf life validation testing conducted for the JAZZ System in accordance with recognized industry standards are also incorporated by reference. In addition, the biocompatibility of the device was confirmed in accordance with ISO-10993.

Substantial Equivalence

The JAZZ System is substantially similar to the previously cleared JAZZ System (K133617). The JAZZ System has the same intended uses / indications for use and principles of operation, as well as nearly identical technological characteristics as its predicate device. The modified JAZZ System is designed to function in the same manner as the cleared predicate device. Other than the modification to the sizes of connector available and the minor modifications to the instruments, all other components remain the same as those of the K132287 predicate. The minor technological differences between the JAZZ System and its predicate device raise no new issues of safety or effectiveness, as demonstrated by testing. Thus, the JAZZ System is substantially equivalent.

Conclusions

The subject device presents only minor modifications compared to the previously cleared JAZZ System. The intended use, indications for use, and principles of operation remain the same as the previously cleared system. The subject device is technologically very similar to the predicate device, and the minor modifications do not raise any new types of safety or effectiveness concerns, as confirmed through risk analysis and verification activities. Therefore, the JAZZ System is substantially equivalent.